Healthcare Improvement Scotland | SHTG Advice on health technologies

Health Technology Assessment in Scotland

What evidence do we need?

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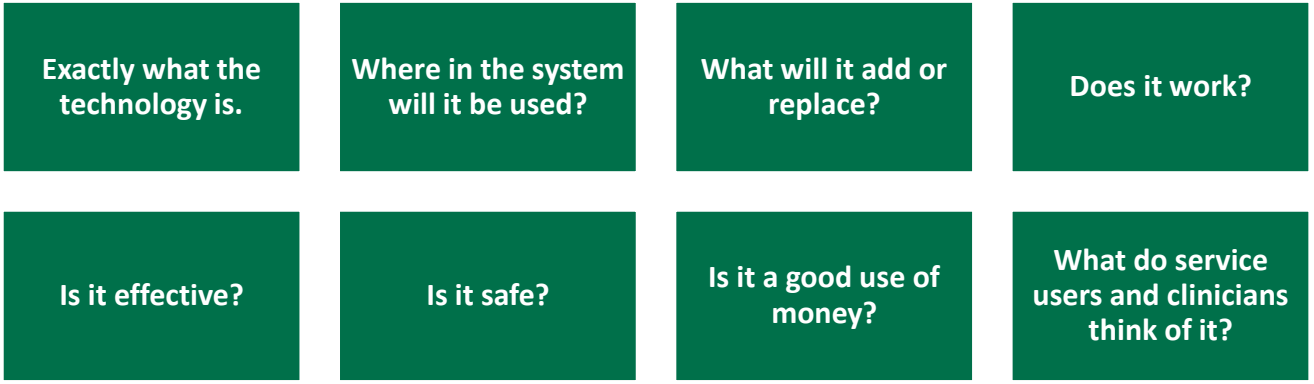
An evidence framework for health technologies

At Scottish Health Technologies Group (SHTG) we're often asked what level or types of evidence are required for a health technology to be given the green light for approval of use in Scotland. This is a difficult question to answer. The nature of health technologies, different types of evidence, and the complexity of decision making means that there is no set threshold for what is 'enough' evidence.

That said, when assessing a health technology, our goal is simple; we want to be sure that the technology improves the quality of health and care in Scotland. Does it make a difference to outcomes that matter? Whether they are service user outcomes, system outcomes or both. We want a full understanding of the technology. This will include gathering information on:



The evidence in response to these questions doesn't have to be complicated, but we do need it to be transparent, understandable, accurate, objective, robust and timely.

What is the SHTG evidence framework and who is it for?

We have shaped an evidence framework that is intended to help evaluators, technology developers, and decision makers better understand what information is required to identify technologies of value to service users and the health and care system.

Our evidence framework has been adapted from existing frameworks including the EUnetHTA core model, and the NICE evidence standards framework for digital technologies. We have drawn from these frameworks and focused on elements that SHTG give consideration to when appraising a technology.

How should I use the evidence framework?

The evidence framework is intended to be used as a reference guide, aligned to the key evidence requirements for health technology assessment (HTA). If the needs under the relevant domains are met, we can determine the value of the technology under review.

The framework can help stakeholders understand how SHTG evaluates health technologies. SHTG advice is based on the quality and quantity of evidence available, across the domains set out in this framework.

Not all domains will be relevant for all technologies. For example, a new service may not require a UKCA or CE mark.

Some domains are particularly important for HTA. For example, technologies that are unable to demonstrate any evidence of clinical effectiveness are not ready for SHTG assessment.

Why is this important?

It is important to make evidence-based decisions. Demands on health and care services are high and resources are limited. Evidence helps us to target our resources on what really makes a difference.

From the very early stages of technology development, planning how to gather evidence to demonstrate value will help with discussions between technology developers and decision makers.

What is a health technology?

This framework is relevant across all health technologies.

> **A `health technology' is an intervention, product or service developed to prevent, diagnose or treat medical conditions; promote health; provide rehabilitation; or organise healthcare delivery.**

This broad definition means that health technologies considered by SHTG include:

SHTG does not consider medicines, which is the remit of the Scottish Medicines Consortium (SMC).

What about digital technologies?

To address domains relevant to digital technologies beyond those in the evidence framework, completion of the NHS England Digital Technology Assessment Criteria (DTAC) supports our decision making. DTAC is an advisory assessment body for commissioning digital health technologies in NHS England and social care services launched in 2021. It sets out baseline standards for clinical safety, data protection, technical security, interoperability and usability and accessibility.

Of the DTAC standards, some are deemed 'must haves' (clinical safety, data protection, medical device regulation) and others are best practice (cybersecurity, interoperability). The DTAC process is outline in Additional domain 1.

SHTG is not a regulator so cannot mandate the regulatory aspects of DTAC.

Implementation

The purpose of HTA is to inform decision making. The value and impact of HTA is strongly linked to the implementation of its recommendations.

Evidence framework

Five domains are set out in this evidence framework. These are:

Domain 1: The technology and its value

Domain 2: Safety, acceptability and credibility

Domain 3: Demonstrating the performance of the technology

Domain 4: Capturing the cost and value for money of the technology, and

Additional domain 1: Digital Technology Assessment Criteria (DTAC)

Contact

For more information on the Scottish Health Technologies Group, contact the team at his.shtg@nhs.scot or visit our webpages at shtg.scot.

Domain 1: The technology and its value

What do we need to see?	What does this look like?

An overview of the technology.	• A clear description of the technology.
	  ○ What is the purpose of the technology?
	  ○ What is the stage of development of the technology?
	  ○ Is the technology already in use?
	  ○ In what context and to what extent is it in use?
	  ○ What geographical variations are there in its use?
	• A description of the health condition (if applicable).
	  ○ What are the symptoms of the health condition?
	  ○ What impact does the health condition have on the service user?
	  ○ What is the impact of the health condition for the health and care sector?
	• A description of the target population.
	  ○ What is the size of the target population? This could be a description of the prevalence and incidence of the relevant health problem, or experts' estimates if this is not available.
	  ○ Why would a person use the health technology?
	  ○ Who cannot or should not use the health technology?

What do we need to see?	What does this look like?

A description of the pathway of care, that is, before the introduction of the new technology.	• What are the current technologies (comparators) within the existing pathway of care(s)?
	  ○ Describe them all, if there is more than one.
	  ○ Describe the existing pathway(s).
	  ○ It can be helpful to provide a flow chart or diagram.
	• What if there is no existing pathway of care or system processes?
	  ○ Describe the potential impact of introducing the health technology on existing healthcare systems.

A description of the proposed pathway of care based on the introduction of the technology.	• A description of the proposed pathway.
	  ○ Will the technology replace an existing technology or step in current practice?
	  ○ Will the technology complement current practice or be in addition to current practice?
	  ○ At what stage of the care pathway will the technology be used?
	  ▪ For example, will it be used in primary care and/or secondary care?
	• Changes to current pathways or practice.
	  ○ What changes would need to be made to infrastructure, service provision and workforce to adopt the technology?
	  ○ What changes will be needed to operate and maintain the proposed pathway or process using the technology?
	  ○ Will there be a need for training and education for health and care professionals or the target population?
	  ○ What are the barriers and enablers to the use of the technology?

What do we need to see?	What does this look like?
A description of the value proposition of the technology.	• The health benefits and other outcomes (such as system efficiency, care outcomes, or structural and procedural effects) associated with current practice. • The anticipated health benefits and impact on other outcomes (such as system efficiency, care outcomes, or structural and procedural effects) associated with the technology. • The costs and resource use associated with current practice. • The expected costs and resource use associated with the new technology.
A description of the clinical need for the technology.	• Does the technology address a current priority area for the health and care in Scotland? ○ For example, does it fit with national strategy? • What is the evidence for the clinical need for this technology? • Is there evidence of the support and interest for this intervention in the health and care community? • Does the technology fix a problem applicable to a small number of health boards, or is it applicable to all boards?

Domain 2: Safety, acceptability and credibility

What do we need to see?	What does this look like?
A description of how the technology complies with relevant regulatory standards.	• Does the technology have regulatory approval (that is, UKCA or CE marking)? • Is documentation that all safety and quality standards (relevant to the device classification) have been met provided?

A description of any safety considerations.	• What are the safety concerns?
	  ○ Related to the technology or comparator.
	  ○ How do these safety concerns compare with current practice?
	  ○ Does the frequency or severity of harms change over time or in different settings?
	  ○ What are the risks for the public and the environment that when using the technology?
	  ○ Are there any harms related to dosage or frequency of applying the technology?
	• Managing the risks.
	  ○ How can the safety risks for service users, professionals and the environment be reduced?
	  ○ Are there any service user groups that are more likely to be harmed through the use of the technology?
	  ○ Are there any safety risks to staff when using the technology compared with current practice?
	• Screening and diagnosis technologies.
	  ○ What is the impact of false positive, false negative and incidental findings, from the viewpoint of service user safety?

What do we need to see?	What does this look like?
A description of how intended service user groups were involved in the development of the technology.	• How were representatives from intended service user groups involved in the design, development or testing of the technology?

A description of inequalities.	• How have health inequalities been considered in the design of the technology?
	• Are there any positive impacts of the technology on health inequalities?
	  ○ Is there evidence that the technology challenges health inequalities in the UK health and social care system?
	  ○ Is there evidence that the technology improves access to care among hard-to-reach populations?
	  ○ Is there evidence that the technology promotes equality and eliminates unlawful discrimination?
	  ○ Is there evidence that the technology fosters good relations between people with protected characteristics (as described in the Equalities Act 2010) and others?
	  ○ Are there any efforts to reduce the negative impacts of the technology on health inequalities?

A description of the environmental sustainability considerations	• What are the expected environmental sustainability benefits and negative impacts from using the technology? • Is an analysis of the environmental outcomes available (for example, comparative CO2e estimates)?
A description of the credibility of the technology with UK health and care professionals, and service users or the public.	• Is there evidence that relevant health or care professional(s) working in the UK health and social care system have been involved in designing, developing or testing the technology, or given their support to the deployment of the technology? • Is there evidence that the technology is viewed as useful by professional experts or expert groups?

Domain 3: Demonstrating the performance of the technology

What do we need to see?	What does this look like?

Evidence of clinical benefits.	• Demonstrating benefits.
	  ○ Are there high quality, relevant studies available?
	  ○ Were these studies done in a setting relevant to the Scottish health and social care system?
	  ○ Did the studies show improvements in relevant outcomes?
	• For technologies that treat a specific condition.
	  ○ Are there interventional studies (experimental or quasi-experimental design) that support the claimed benefits of the technology?
	  ▪ Did they show improvements in relevant outcomes?
	  ▪ Is the comparator a care option that reflects the current NHSScotland care pathway?
	  ▪ In a novel, innovative or transformative technology, the setting may not reflect the Scottish pathway, but it should still be able to demonstrate excellent performance and high value.
	• For technologies that diagnose a specific condition.
	  ○ Do they support the claimed benefits of the test?
	  ○ This may include test accuracy studies, using an appropriate reference standard, or a concordance study to show agreement with current practice.
	• When it is not possible, ethical or relevant to conduct an interventional study.
	  ○ Are there observational studies?
	• Understanding service users' and healthcare professionals' views of the technology.

What do we need to see?	What does this look like?
	○ Are there qualitative studies or surveys available? • When it's important to know how technology works in the real world. ○ Real-world evidence may help to reduce uncertainty. ▪ For example, is the technology expected to have high costs or large system impacts, such as requiring significant service redesign? • Is any published evidence described of real-world benefits transferable to the Scottish population? • Is there evidence that the technology has been evaluated in the Scottish health and social care system? (see Real-world evaluation section).
Real-world evaluation.	• Is there evidence that the technology has been evaluated in the Scottish health and social care system? ○ Was the technology acceptable to service users (including clinicians, service users and caregivers)? ○ Did the technology perform its intended purpose to the expected level? ○ Did the technology successfully integrated into current service provision or current best practice? ○ Did the technology cause any unintended negative impacts on service users or services? ○ Did the technology show improvements in outcomes (costs saved, efficiencies achieved and health and care improvements)? ○ Was the technology used in line with expectation (who, how, for how long)?

What do we need to see?	What does this look like?
Information about service users' and caregivers' experiences of the intervention.	• Are there descriptions of individuals' experiences of living with the condition? • What expectations do individuals' have of the technology including what they expect to gain? • What are individuals' and caregivers' experiences of using the technology? • Are service users and caregivers' satisfied with the technology? • Does the use of the technology affect the service user's capability and possibility to exercise autonomy? • Is there a need for any specific interventions or supportive actions concerning information in order to respect service user autonomy when the technology is used? • Is information available that the service user needs to make informed decisions about the technology? • Does use of the technology challenge or change healthcare professional values, ethics or traditional roles that could impact the relationship between the service user and the healthcare professional? • Does use of the technology affect human dignity? • Does use of the technology affect the service user's moral, religious or cultural integrity? • Does the technology invade the privacy of the service user? • What could prevent a group or person from gaining access to the technology? • Is there any information that needs to be communicated to service users to improve adherence?
The measurement plan for collecting usage data and evidence.	• Is there a plan, agreed between the evaluator and developer, for ongoing data collection, particularly around ongoing use of the technology and service-user outcomes? • Is there a plan, agreed between the evaluator and developer, on post-deployment reporting of changes in performance and safety?

Domain 4: Capturing the cost and value for money of the technology

What do we need to see?	What does this look like?

A budget impact analysis.	• Is there agreement around the size of target population and estimates on the uptake of the technology?
	• What are all direct costs of the technology and its implementation?
	  ○ What is the cost of the technology, including cost of the technology (purchasing, updating and maintenance)?
	  ○ What are the costs of staffing and training?
	  ○ What are the costs of the supportive IT infrastructure needed to implement the technology?
	• What are all the direct costs associated with the comparator (current practice)?
	• What are the relevant indirect costs associated with the technology and the comparator, reference test or current practice?
	• Is there an exploration of the uncertainty of the estimate obtained from the budget impact analysis by varying the assumptions used, to investigate how these variations impact the analysis?

An economic evaluation.	• A cost effectiveness analysis. For example:
	  ○ a cost-utility analysis
	  ○ a cost-consequence analysis, and
	  ○ an exploration of the uncertainty of the obtained estimate by using sensitivity and scenario analyses.

Additional domain 1: Digital Technology Assessment Criteria (DTAC)

Additional information required for digital technologies.

What do we need to see?	What does this look like?

A completed NHS Digital Technology Assessment Criteria (DTAC).	• The NHS DTAC sets out specific standards for digital healthcare technologies. If you want your technology to be used in the NHS and social care, it should meet these standards. The DTAC focuses on five core areas:
	  ○ clinical safety
	  ○ data protection
	  ○ technical assurance
	  ○ interoperability, and
	  ○ usability and accessibility.
	• Using the DTAC will give staff, service users and the public confidence that the digital technology they use meets national minimum standards across the core areas.
	• Completing the DTAC will help technology developers to prepare for assessment. The assessments may be conducted by SHTG, or by local health and care organisations.
	• This helpful YouTube video provides an overview of the DTAC.

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We are happy to consider requests for other languages or formats.
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